

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference  BLP-208PCT		Date of mailing (day/month/year) <b>09 JUN 2005</b> <b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No.	International filing date (day/month/year)	Priority date (day/month/year)	
PCT/US05/00603	09 January 2005 (09.01.2005)	10 January 2004 (10.01.2004)	
International Patent Classification (IPC) or both national classification and IPC			
IPC(7): A61K 9/06, 7/00 and US Cl.: 424/401, 427; 514/969			
Applicant			
BIOLIPID, INC.			

1. This opinion contains indications relating to the following items:

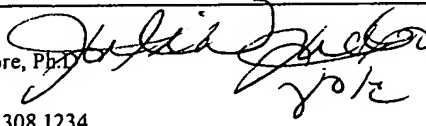
- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☒ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.  
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Gollamudi S. Kishore, Ph.D.  Telephone No. 703 308 1234
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 10 JUN 2005  
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/00603

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
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International application No.

PCT/US05/00603

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 28 and 31-33

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 28 and 31-33 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 28 and 31-33 are multiple dependent claims depending from multiple dependent claims 22-25.

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/00603

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims <u>2, 4, 15-21, 23-27, 29-30, 34-36 and 38</u>	YES
	Claims <u>1, 3, 5-8, 13, 14, 22 and 37</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-27, 29-30 and 34-38</u>	NO
Industrial applicability (IA)	Claims <u>1-27, 29-30 and 34-38</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 3, 5-8, 13-4 and 22-23 lack novelty under PCT Article 33(2) as being anticipated by MAUSNER (US 5,571,503).

MAUSNER teaches eye compositions containing C13-14 isoparaffins, mineral oil, squaline, phospholipids, fatty acid esters, cholesteryl behenate, glycerol and medium chain triglycerides (col. 2, line 45 through col. 7, line 5, col. 9, line 33, Tables and claims).

Claim 37 lacks novelty under PCT Article 33(2) as being anticipated by KAUFMAN (US 4,923,699).

KAUFMAN discloses a method of treating dry eye using ointments containing polar lipid, lecithin and non-polar lipid, cholesterol (abstract, col. 5, lines 33-36, col. 10, lines 60-68, col. 17, line 3 and claim 22).

Claims 2, 4, 9-10, 15, 17-21 and 34-38 an inventive step under PCT Article 33(3) as being obvious over MAUSNER cited above.

As pointed out above, MAUSNER teaches eye compositions containing C13-14 isoparaffins, mineral oil, squaline, phospholipids, fatty acid esters, cholesteryl behenate, glycerol and medium chain triglycerides (col. 2, line 45 through col. 7, line 5, col. 9, line 33, Tables and claims). The amounts of the components in MAUSNER appear to differ from instant amounts. For example, the amounts of phospholipids taught by MAUSNER are up to 1 % and not instantly claimed 2 to 10 %. However, in the absence of showing unexpected results it is deemed obvious to one of ordinary skill in the art to vary the amounts of the components of MAUSNER to obtain the best possible results. MAUSNER also does not teach the composition in an ointment form without water. However, it is evident from MAUSNER's tables, water is added to dissolve the water soluble components such as plant extracts and it would have been obvious to one of ordinary skill in the art to prepare a composition in the ointment form if the water soluble components are not necessary. MAUSNER also does not teach instantly claimed mode of administration. In the absence of showing unexpected results, the mode of administration is deemed to be the choice of the artisan.

Claims 11, 12, 16, 22-31 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of KORB et al.

MAUSNER does not teach the inclusion of beeswax in the compositions. Such an inclusion however, would have been obvious to one of ordinary skill in the art since the reference of KORB shows that beeswax is routinely used in combination with hydrocarbon oils for the treatment of dry eye conditions (see abstract, col. 3, lines 15-23, col. 4, lines 6-42, col. 5, lines 7-48 and Examples 45-48).

Claims 27 and 37 lack an inventive step under PCT Article 33(3) as being obvious over MAUSNER in view of KAUFMAN (US 4,923,699) cited above.

What is also lacking in MAUSNER is the teaching of the inclusion of drugs such as cyclosporin.

KAUFMAN while disclosing ophthalmic ointments for dry eye treatment teaches the inclusion of immunosuppressants such as cyclosporin. The compositions further include polar lipid, lecithin and non-polar lipid, cholesterol (abstract, col. 5, lines 33-36, col. 10, lines 60-68, col. 17, line 3 and claim 22). The inclusion of cyclosporin would have been obvious to one of ordinary skill in the art since such an inclusion would provide an immunosuppressant action if needed.

Claims 1-27, 29-30 and 34-38 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.